

**Claims Rejection Under 35 USC § 102(b)**

Claims 5-9 remain rejected under 35 USC § 102(e) as being anticipated by commonly owned Singer et al. (US 5,364,616). The Examiner contends that '616 teaches a method for treatment and prevention of oral cavity diseases of gingivitis and periodontitis comprising topical administration of a composition comprising an antimicrobial anti-plaque agent and a histamine-2 receptor antagonist and that the whole body health benefits are inherent in the method outlined in '616.

Applicants respectfully traverse the Examiner's rejection of the claims in view of the Singer et al.

Firstly, Applicants will address the Examiner's point that the present claimed "new use" of promoting whole body health is simply a statement purpose and intended result and is therefore not considered limiting. The Examiner cites *Bristol-Myers Squibb v. Ben Venue Laboratories* 58 USPQ 2d 1508 (CAFC 246 F.3d 1368 2001) for the proposition that:

*[The] preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are nonlimiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use of process should be considered limiting because it distinguishes process over prior art.*

*Bristol* is distinguishable over the present invention in that the purpose, namely "whole body health", is not known or suggested by the art. Indeed the *Bristol* Court concedes that new uses of known process may be patentable.

*Bristol* is correct that new uses of known processes may be patentable. See 35 U.S.C. § 101 (1994) (*Whoever invents or discovers any new and useful process... may obtain a patent therefore.*); 35 U.S.C. § 100(b) (1994) (*"The term "process" means process, art or method and includes a new use of a known process, machine, manufacture, composition of matter, or material."*).

However, the court continues, *"the claimed process here is NOT directed to a new use; it is the same use, and it consists of the same steps as described by Kris [the prior art reference].... Bristol has done no more than claim a result (efficacy) of three-hour paclitaxel infusions in cancer patients As in May, the purpose -- treating cancer-- is no different from the purpose disclosed by Kris."* *Bristol* at 1377.

Turning to the claims of the present invention, Applicants assert that the art fails to teach or suggest the treatment of whole body or systemic health. The present purpose --promoting whole body health-- is distinguishable over *Bristol* in that the purpose is NOT disclosed in the prior art. In contrast to the facts of *Bristol*, Applicants do NOT attempt to claim "newly discovered results of a known process directed to the same purpose" but rather, claim a novel and unobvious *process* by virtue of a new use or a different purpose. Clearly, promoting systemic or whole body health is a different purpose than treating local or nonsystemic conditions, i.e., gingivitis or periodontitis, as disclosed by Singer, et al. There is no teaching whatsoever in Singer et al. of directing topical administration of a composition comprising an antimicrobial for the purpose of promoting systemic or whole body health. Therefore, Applicants assert

that the present claimed method of promoting whole body health is patentable in accordance to well-established Federal Circuit jurisprudence.

The present claims define a method for a "new use", i.e., promoting whole body health, by topical administration to the oral cavity of a composition comprising an antimicrobial agent optionally with a H2 antagonist. By the present claimed method, spread into the bloodstream and other parts of the body of pathogenic oral bacteria and associated harmful substances including toxins and endotoxins is prevented or minimized. The result is a decrease in the causative factors for certain diseases and a corresponding decrease in the risk of development of these systemic diseases, such as heart disease. Thus, the present claims are directed to a new use for a method that traditionally has been used solely for locally treating or preventing bacteria-mediated diseases and conditions of the oral cavity.

Applicants respectfully submit that the present method claims directed to a new use of topical administration of an antimicrobial agent optionally with a H2 antagonist are novel and unobvious in view of the cited reference. There is no disclosure nor any suggestion in Singer et al. with regard to whole body or systemic health, much less that the present antimicrobial containing compositions administered topically to the oral cavity would promote whole body health by decreasing causative or risk factors that are involved in the development of certain systemic diseases. The benefits to systemic health when the method of treatment is by topical administration as opposed to systemic administration have not been appreciated in Singer et al. nor in any other prior disclosure. The present methods are based on the discovery that topical administration of an antimicrobial agent affords unanticipated benefits for preventing oral pathogens and their products from entering into the systemic circulation and from prompting the systemic inflammatory mechanisms and complications that contribute to systemic diseases/disorders such as atherosclerosis, stroke, diabetes, and low birth weight infants.

Applicants also traverse the Examiner's contention that the present method claims are not patentable because the results of the claimed methods, i.e., "whole body health benefits", are inherent.

The present method claims fall within the definition under 35 U.S.C. § 100(b) for a patentable "process" which means process, art or method, and includes a *new use of a known process, machine, manufacture, composition or matter or material*. (emphasis added), as acknowledged by the Court in *Bristol-Myers Squibb v. Ben Venue Laboratories*. See also *Howes v. Great Lakes Press Corp.*, 679 F.2d 1023, 1029 (2d Cir.), which found that Howes' claim to a method which makes possible the faithful transfer of color art work to fabric by means of treated heat transfer paper was patentable because Howes created a *new use of a known process*. Similarly, *claims drawn to a method for using either an old or "obvious" composition, wherein the method has unobvious beneficial or useful effects, have been found patentable even though the composition itself could not be patented*. [See *In re Shetty*, 566 F.2d 81, 83, 195 USPQ 753, 754 (CCPA 1977); *In re Legator*, 53 CCPA, 729, 352 F.2d 377 (1965); *Joseph Bancroft & Sons Co. v. Watson*, 170 F. Supp. 78 (D.D.C. 1959), 120 USPQ 265]

Applicants respectfully submit that the present claimed methods involving topically administering a composition comprising an antimicrobial agent optionally comprising a H2 antagonist have new and unobvious beneficial effects, and are therefore patentable as a new use of a process even if such process

were known. The benefits to systemic health when the method of treatment is by topical administration of the present compositions and not by systemic administration have not been appreciated in Singer et al. nor in any other prior disclosure.

Applicants further submit that the issue of inherency which the Examiner has used to make the rejection is untenable in this instance, wherein the "new use" of promoting whole body or systemic health via a method that involves topical administration of antibacterial actives as opposed to systemic administration is totally unappreciated in the prior art. The Examiner's attention is respectfully directed to the case of *In re Shetty*, 566 F.2d 81, 83, 195 USPQ 753, 754 (CCPA 1977), wherein the claimed method of curbing appetite by administering certain adamantane compounds was found to be patentable over prior references that disclosed administering similar compounds to achieve antiviral effects in amounts encompassing the amounts intended and claimed by Shetty for appetite suppression. The PTO had held that the compounds used by Shetty are obvious over the references and the benefit of curbing appetite claimed by Shetty is inherent. The CCPA rejected the PTO's position and reversed the rejection of Shetty's method claims for curbing appetite, stating the following:

Local  
appetite Supp

*We cannot accept this conclusion. The issue here is whether the claimed method of curbing appetite would have been obvious. That appellant's "amount effective to curb appetite" corresponds to or inheres in Narayanan's amount "to combat microbial infestation" does not persuade us of the obviousness of appellant's method. As this court said in In re Naylor, 54 CCPA 902, 905-06, 369 F.2d 765, 768, 152 USPQ 106, 108 (1966):*

*[Inherency] is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result.*

Applicants further direct the Examiner's attention to the directive under MPEP 2112 and 2131.02 Section III, that the Examiner must provide rationale or evidence to show inherency. As stated therein:

*"In relying upon the theory of inherency, the examiner must provide a basis in fact and or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."*

*"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish that result or characteristic."*

There must be evidence to support the Examiner's allegation that a characteristic not disclosed in cited reference is inherent. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill.

As in the Shetty case, the Examiner has not provided any evidence whatsoever to establish that one of ordinary skill in the art would appreciate or recognize the beneficial effects, i.e., promoting systemic or

whole body health of the present claimed method. There is no disclosure or suggestion in Singer et al. that a method involving topical administration of a composition containing the recited antimicrobials as opposed to systemic administration would be useful in promoting systemic health. In fact, all of Singer's disclosure relate to the use of H2 antagonist compounds to treat periodontitis and gingivitis. The presence of an antimicrobial antiplaque agent is optional. Accordingly, the rejection of the claims under §102(b) over Singer et al. cannot stand.

Finally, Applicants submit that it is well established that a second medicinal use of a substance already suggested or known to be useful in treating a human or animal disease is patentable as a method of use under US patent law. While there are numerous examples, Applicants cite the granting of US 6,100,270 (to Pfizer) with method claims for a second medicinal use, i.e., treating male erectile dysfunction, for sildenafil compositions, which have previously been patented for the treatment of many conditions including angina, hypertension and congestive heart failure (US 5,250,534 and US 5,346,901). The method in this case involves the same method of oral administration of the compositions containing the active sildenafil. The second or new use is the basis for patentability of the method. As another example, claims to methods of treating male pattern baldness using minoxidil were patentable, even if minoxidil compositions had already been patented for treating hypertension. Further, claims to a process for obtaining increased meat, milk, egg or wool production in healthy animals comprising the administration of a minoxidil composition to a healthy animal were allowed. Again, methods of administering minoxidil for new uses were patentable.


The present method claims are likewise directed to a new or second use --promoting systemic or whole body health-- by topical administration of antimicrobial compounds and are patentable in accordance with US patent practice.

#### CONCLUSION

Applicants respectfully request reconsideration of this application, withdrawal of the claims rejections under §102(b) and allowance of all application claims.

Respectfully submitted,

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